REMARKS

Claims 6-7 and 12 are pending in the present application.

The rejections of Claims 6, 7, and 12 under 35 U.S.C. §103(a) over:

(a) Fox in view of Waki et al and further in view of Applicants' alleged admission;

(b) Levy et al in view of Waki et al and further in view of Applicants' alleged admission; and

(c) Buechler in view of Waki et al and further in view of Applicants' alleged admission;

are obviated in part by the present amendment and traversed in part.

Applicants submit that the art of record does not disclose or suggest a container for an immunoassay that is coated with an ultra-hydrophilic polymer which is a copolymer containing a (2-methacryloyloxyethylphosphorylcholine) polymer subunit, as presently claimed (see Claim 12). Specifically, Applicants submit that the art of record fails to disclose a copolymer containing a (2-methacryloyloxyethylphosphorylcholine) polymer subunit, much less a container for an immunoassay, wherein the inner surface, which is to contact a specimen for immunoassay, of the container is formed from or coated with the this copolymer and wherein the saturation adsorption amount of molecules used for the assay, on at least an inner surface of the container, is 1×10^{-3} pmol/cm^2 or less.

Citing In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974), MPEP §2143.03 states: "To establish a prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." Applicants submit that the disclosure of the art of record, in any combination, fail to meet this requirement and, as such,

the artisan would have no reasonable motivation to produce a container for an immunoassay as presently claimed or any reasonable expectation of the advantageous obtained thereby.

The Examiner cites Buechler, Fox, and Levy et al as providing containers for immunoassay, while Waki et al disclose copolymers containing a 2-methacryloyloxyethylphosphorylcholine subunit. Although Waki et al disclose the use of a copolymer closely resembling that of the present invention, this reference does not disclose or suggest that at least an inner surface of the container is coated beforehand with such a copolymer. Moreover, the copolymer disclosed by Waki et al is soluble in water, not insoluble in water. Further, at no point do Waki et al disclose or suggest that the saturation adsorption amount of 1×10^{-3} pmol/cm^2 or less as presently claimed.

For the Examiner's convenience and reference, Applicants submit herewith a copy of Table 5 from Waki et al, which relates to the adsorption of plasma protein, in which the adsorption of plasma protein has been recalculated in terms of the unit "pmol/cm^2" (i.e., the units in the claimed invention). These data clearly show that there is a significant difference between the adsorption amount of plasma protein disclosed by Waki et al and the range claimed in the present invention. In fact the adsorption amount disclosed by Waki et al (i.e., 2-90 pmol/cm^2) is approximately 1000-10000 times more than the saturation adsorption amount defined by the present invention. Therefore, Applicants submit that there is no reasonable expectation based on the disclosure of Waki et al that the saturation adsorption amount as presently claimed can ever be attained. None of Buechler, Fox, and Levy et al compensates for deficiency or provides motivation to attain such a limitation.

Further, the container for a immunoassay of the present invention comprises a significantly specific feature such that at least the inner surface of the container, more specifically the entire surface of the container, is coated beforehand with an insoluble ultra-

hydropbilic polymer containing a 2-MPC polymer and the saturation adsorption amount of protein falls within the range of 1 x 10^{-3} pmol/cm^2 or less. More specifically, the container of the present invention absorbs almost no protein on its inner surface and therefore never becomes a solid state. For immunoreactions to be effectively performed by use of the container of the present invention, it is necessary either to employ a homogeneous assay or to incorporate other solid phase substances (e.g., beads) in the container. This technical conception is neither disclosed nor suggested in the art of record.

In view of the foregoing, Applicants respectfully request withdrawal of these grounds of rejection.

The rejections of Claims 7 and 12 under 35 U.S.C. § 112, second paragraph, is obviated in part by amendment and traversed in part.

Claim 12 as currently presented clearly defines the surface of the container to be coated with the copolymer, as well as the relationship of the same to the specimen to be contacted. Further, Applicants note that the present invention is predicated on the finding that a container for an immunoassay can be significantly improved by a method under which the inner surface is coated beforehand with an insoluble ultra-hydrophilic polymer containing a 2-MPC polymer and the saturation adsorption amount needs to fall within the range of 1 x 10^{-3} pmol/cm^2 or less, which is what is presently claimed.

Applicants maintain that that the saturation adsorption amount is, in fact, a function of the container and are defined by the ultra-hydrophilic polymer selected for coating the container. Applicants refer the Examiner to page 7, line 18 to page 8, line 26 of the specification, which clearly provides guidance for the selection of the criteria alluded to by the Examiner (i.e., The identities of the molecules used (including size), the temperature,

concentration of the solution, and the pH of the solvent). Further, page 7, line 18 to page 13, line 1, provide a detailed description, which clearly underscores that role played by the claimed ultra-hydrophilic polymers. Moreover, Applicants refer the Examiner to the Examples (pages 13-23), which provide the artisan with a detailed roadmap of experiments that can be used to assess whether the claimed saturation adsorption threshold has been met.

Despite the foregoing, it is the Examiner's position that the saturation adsorption amount is a function of the molecules placed into the container and not of the polymer used in the container. The Examiner's position is based on the disclosure at page 7, line 18 to page 8, line 8 of the specification, which states that the adsorption amount varies with the "identify of the molecules, temperature, concentration of the solution, and the pH of the solvent." However, the Examiner has misunderstood the distinction between "adsorption amount" and "saturation adsorption amount." Although there may be some merit that adsorption amount varies as a function of specific conditions. However, what is claimed is the *saturation* adsorption amount and the *saturation* adsorption amount is a fixed quantity relating to a maximum adsorption amount that a given coated surface can support irrespective of the conditions assayed. As such, the saturation adsorption amount ***is*** a property of the polymer coating in the container.

The saturation adsorption amount of the inner surface is an important factor for the container for an immunoassay of the present invention is concerned, and the degree thereof varies depending on the type and nature of the polymer that has been used therein for coating. However, this degree is never affected by any observation conditions. Furthermore, the saturation adsorption amount continues stable insofar as the inner surface of the container is coated beforehand with the claimed polymer. This is because the polymer used in this invention is insoluble in water and therefore is not readily eluted by any generally available

immunoreactions nor does it readily change under the ordinary conditions of immunoreactions. Additionally, Applicants note that the observation conditions employed in this invention are substantially identical to those commonly used in this field, because this invention intends to provide a container for an immunoassay. Under none of such conditions does change the saturation adsorption amount.

Applicants remind the Examiner that definiteness of claim language must be analyzed, not in a vacuum, but in light of:

(A) The content of the particular application disclosure;

(B) The teachings of the prior art; and

(C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made (MPEP §2173.02).

In view of the foregoing, Applicants believe that the language of the claims are such that a person of ordinary skill in the art could interpret the metes and bound of the claims so as to understand how to avoid infringement (MPEP §2173.02), especially when interpreted with the specification as a guide.

For the foregoing reasons, Applicants submit that the present invention is definite as defined in 35 U.S.C. §112, second paragraph. Withdrawal of this ground of rejection is requested.

Applicants request that the Examiner provide acknowledgment that the references cited on the Information Disclosure Statements filed on February 14, 2002 and July 28, 2004, have been considered. Applicants respectfully request that the Examiner acknowledge consideration of same by providing Applicants with initialed copies of the Form PTO-1449 filed on the aforementioned days. In the event that the Office has misplaced the Information

Disclosure Statements, the Examiner is requested to contact the undersigned by telephone to avoid further delay in examination of this application.

Applicants submit that the present application is in condition for allowance. Early notification to this effect is respectfully requested.

Respectfully submitted,

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TABLE 5

Examples & Comperative Examples	Adsorption of Plasma Protein(pmol/cm^2)					
	Concentration of Human Plasma Protein			Concentration of Human Plasma Protein(1/10)		
	Albumin	γ-globulin	Fibrinogen	Albumin	γ-globulin	Fibrinogen
Ex.1-1	61.0 ± 20.4	24.3 ± 7.9	4.6 ± 1.9	22.4 ± 5.1	7.8 ± 0.7	3.0 ± 1.3
Ex.1-2	50.4 ± 21.4	30.5 ± 11.4	4.1 ± 1.1	17.6 ± 1.0	12.4 ± 1.1	2.1 ± 0.4
Ex.1-3	50.4 ± 21.4	30.5 ± 11.4	4.1 ± 1.1	17.6 ± 1.0	5.7 ± 1.1	2.1 ± 0.4
Ex.1-4	62.3 ± 3.4	32.4 ± 10.9	4.6 ± 1.1	20.0 ± 1.9	8.6 ± 1.5	1.3 ± 1.7
Ex.1-5	50.0 ± 21.7	29.7 ± 10.9	4.5 ± 1.2	19.0 ± 1.1	5.5 ± 1.4	2.1 ± 0.6
Ex.1-6	61.4 ± 3.1	28.9 ± 10.3	4.3 ± 0.8	19.6 ± 3.1	8.8 ± 1.3	1.3 ± 1.3
Ex.1-7	64.6 ± 18.9	22.0 ± 2.3	4.9 ± 1.3	23.9 ± 7.6	8.7 ± 1.3	2.8 ± 0.1
Ex.1-8	50.4 ± 19.3	27.8 ± 7.7	5.6 ± 1.6	19.9 ± 3.7	6.8 ± 1.5	2.8 ± 0.6
Ex.1-9	49.0 ± 26.4	27.4 ± 7.7	3.8 ± 1.0	18.7 ± 1.3	6.8 ± 1.5	2.7 ± 0.6
Comp.Ex. 1-1	65.3 ± 20.6	24.3 ± 8.3	5.5 ± 1.6	23.9 ± 6.6	8.8 ± 0.7	3.3 ± 1.0
Comp.Ex. 1-2	53.1 ± 15.7	29.7 ± 8.3	6.0 ± 1.3	21.9 ± 2.4	7.7 ± 1.5	2.9 ± 0.7
Comp.Ex. 1-3	52.6 ± 21.7	29.9 ± 10.8	6.2 ± 0.9	21.9 ± 2.6	6.6 ± 1.5	3.3 ± 0.7
Comp.Ex. 1-4	67.4 ± 21.7	22.2 ± 2.1	6.1 ± 1.6	26.9 ± 9.0	9.9 ± 1.2	3.0 ± 0.2
Comp.Ex. 1-5	67.3 ± 24.4	20.9 ± 3.0	6.7 ± 2.1	24.4 ± 6.1	10.0 ± 1.1	2.9 ± 0.5
Comp.Ex. 1-6	76.1 ± 26.0	32.1 ± 3.7	10.5 ± 2.9	34.7 ± 7.9	14.9 ± 1.2	5.1 ± 0.6
Comp.Ex. 1-7	75.6 ± 23.7	33.3 ± 2.9	10.6 ± 3.3	33.3 ± 5.6	15.4 ± 1.3	4.9 ± 0.4
Comp.Ex. 1-8	66.3 ± 26.9	20.9 ± 3.5	6.2 ± 2.1	27.0 ± 9.1	10.1 ± 1.3	3.1 ± 0.3
Ex.2-1	57.3 ± 17.7	23.5 ± 8.0	4.2 ± 1.6	21.0 ± 5.0	7.2 ± 0.8	2.2 ± 1.0
Ex.2-2	47.9 ± 20.9	29.7 ± 10.3	4.0 ± 1.0	17.0 ± 1.4	5.1 ± 0.6	2.3 ± 0.4
Ex.2-3	47.6 ± 17.9	27.3 ± 8.3	3.9 ± 0.7	19.0 ± 2.3	6.5 ± 1.4	2.6 ± 0.3
Comp.Ex. 2-1	64.3 ± 17.4	24.0 ± 7.6	4.6 ± 1.6	23.6 ± 5.1	7.5 ± 1.5	3.2 ± 0.9
Comp.Ex. 2-2	50.3 ± 7.4	30.3 ± 5.0	5.9 ± 1.8	20.7 ± 3.9	7.3 ± 2.2	2.8 ± 1.3
Comp.Ex. 2-3	51.4 ± 16.0	28.9 ± 6.8	5.9 ± 1.0	20.9 ± 4.0	7.1 ± 1.7	3.0 ± 1.0
Ex.3	65.0 ± 21.3	30.1 ± 12.1	7.4 ± 1.1	21.4 ± 1.6	8.7 ± 1.4	2.8 ± 0.4